THE FUTURE OF CLINICAL DEVELOPMENT



PRAHEALTHSCIENCES

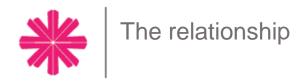


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- Layout is a combination of source data and CRF data
- Workflow data cleaning SDTM



Combination of Source and CRF data

MEDICATION DOSING			
Treatment description: Single dose oral administratio	n of XXX or placebo as tablet(s) / capsule(s) under fasting conditions		
Treatment [Not Submitted]			
A O Single dose oral administration of XXX or placebo as tablet(s) under fasting conditions B O Single dose oral administration of XXX or placebo as tablet(s) under fed conditions			
Fasting and other requirements met?	O No [Not Submitted] O Yes		
Actual time (hhmm)	EXSTDTC		
Actual Dose	mg EXDOSE		
Number of tablets / capsules	NO in SUPPEX		
[Not Submitted]	Administered by [Not Submitted]		
[Not Submitted]	Checked by [Not Submitted]		
Comments	COVAL when RDOMAIN=EX		



Visit Date:	Visit Name∶∣	DAY -1 P1 VISIT	(0=plar >0=unp	nned, planned)
PHYSICAL EXAMINATION		Wi	nen No is checked, ther	
Actual time (hhmm) PEDTC		PE PE Ye	TESTCD=PEALL and ORRES=NO CHANGE. s is not submitted	
Is there a change from previous ex	PESTAT=NOT DON	O Yes	If yes, please check e	ach item
Body system / part	No/ Yes/ Not exam.	XAMINED If yes, give c	omments	
GENERAL APPEARANCE PEORRES whe PETESTCD=GE	lot ovem	1	Note: If the result is Abnormal then PEORRES=Comment	
SKIN / SUBCUTANEOUS TISSUE PEORRES who PETESTCD=SE	en ot over			

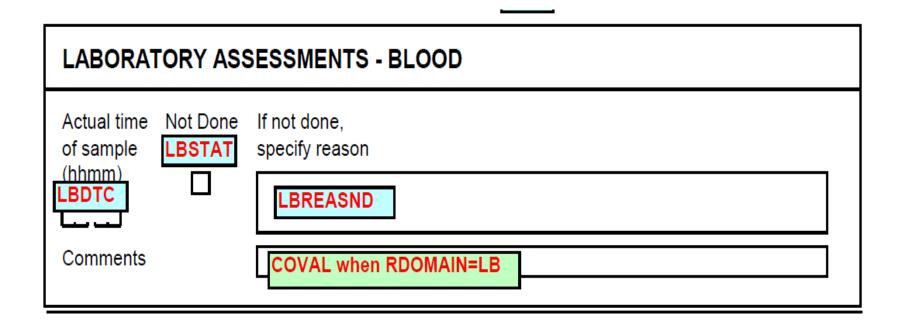


- If composite responses are possible, "No/Yes" questions for each response are preferred to "Check all that apply" questions.
- All code lists displayed in the CRF use or map to current CDISC CT, when available.

Race	O American Indian or Alaska Native O Asian		
RACE, when more than one race selected,	O Black O Native Hawaiian or other Pacific Isla	ınder	
RACE=MULTIPLE and individual responses are RACE1 in SUPPDM RACE2 in SUPPDM	○ White ○ White + Black ○ White + Asian ○ Asian + Black	RACEOTH in SUPPDM, when moone entered, RACE=MULTIPLE a individual responses are RACE1 etc. in SUPPDM	and
	Other please specify		

Not Done & Comments

- The "No/Yes assessment completed" question is preferred to "Check if not done" box
- The general recommendation is that the collection of free text comments is discouraged





Prior and Concomitant medications

CM = Concomitant Medication

	PRA code: TEMP	PL_RDC_B_NL1		
Subject number:	Title (short): Temp	plate for RDC	Bedsite eCRF	NL
Subject Initials:	Sponsor name: PRA			
Page Name: PRE	VIOUS_MEDICATION	Sponsor code:	ABC-123	
Visit Date:	ot Submitted]	Visit Name: SCF	REENING ot Submitted]	(0=planned, >0=unplanned)
PREVIOUS M	EDICATION	MCAT=PRIOR		
	eceive any previous medi	ication (prescription	on or OTC)	No [Not Submitted]
within the last 60	days?		0	Yes
Drug Treatment	Dose per admini-	nit Frequ	CMROUT	Yes Start date End date or ongoing
	Dose per admini-		CMROUT	Yes Start date
Drug Treatment	Dose per admini- stration U		CMROUT Rout	Start date End date or ongoing
Drug Treatment	Dose per admini- stration U CMDOSE		CMROUT ency Rout	Start date E End date or ongoing Start CMSTDTC End CMENDTC CMENDTC
Drug Treatment CMTRT Indication CM	Dose per admini- stration U CMDOSE	CMDOSU	CMROUT ency Rout	Yes Start date End date or ongoing Start CMSTDTC CMENDTC



Prior and Concomitant Medications (2)

Visit Date: [Not Su	Vis 	it Name: OVERVIEW [Not Submitted]	(0=planned, >0=unplanned)
CONCOMITANT	MEDICATION (DRUG	TREATMENT)	MCAT=CONCOMITANT
and follow-up?	ug-treatment reported during	study treatment	O No O Yes [Not Submitted]
Note: relation between CM and AE is described n RELREC Drug Treatment CMTRT	Dose per admini- stration Unit CMDOSE CMI	Frequency	OUTE Start date Route End date or ongoing Start CMSTDTC
	INDC	or AE # [Not Subm	End CMENDTC
Drug Treatment Indication	Dose Unit	or AE #	Start CMENRF= AFTER when checked